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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,649	07/28/2003	Jeffrey M. Besterman	MET-011DV	4430

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,649

Applicant(s)

BESTERMAN ET AL.

Examiner

Robert Shiao

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 11/01/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 16-18 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 16-18 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/26/04, 12/29/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment of claims 22-23, cancellation of claims 1-4, 8-15, 19-21, and 25-50 in the amendment filed on November 01, 2005, is acknowledged. Claims 5-7, 16-18 and 22-24 are pending in the application.

2. The identifiers of claims 5-7, 16-18, and 24 are not acceptable. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled.

Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered), see Patent Rules 1.121 (c). Correction is required.

Responses to Election/Restriction

3. Applicant's election with traverse of a group III claims 5-7, 11, 16-18 and 22-24, in part, i.e., now are 5-7, 16-18 and 22-24, in part, in the reply filed on November 01, 2005, is acknowledged. The traversal is on the ground(s) that examining Group II-IV, VI

and VIII would not present additional burden on the Examiner. This is not found persuasive, and the reasons are given, *infra*.

Status of the Claims

4. Claims 5-7, 16-18 and 22-24 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 5-7, 16-18, and 22-24, in part, drawn to compounds/compositions of formula (II), wherein the variable X does not represent fused heterocyclic, heteroaromatic ring, or heteroarylene thereof, classified in class 514/549/558 with various subclasses.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds/compositions contain varying fused heterocycle, heteroarylene, or heterocyclic of the variable X of the formula (II) having azepane, thiophene, or furanyl moiety, which differ from those of the elected invention having triazole or indazol moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 540 subclass 450(+) (azepane), class 549 subclass 83(+) (thiophene), class 549 subclass (200+) furan, etc. Therefore, again, the compounds which are withdrawn from consideration as being for

non-elected subject matter differ materially in structure and composition and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 5-7, 16-18, and 22-24, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 5-7, 16-18, and 22-24, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter

"antibiotics agent" or "beta-lactam antibiotic", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 23-24, lines 1-2, and page 21, lines 13-19 of the specification.

6. Claim 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of use of the instant compositions of compounds of formula (II) further comprising an antibiotic agent penicillins, does not reasonably provide enablement for the instant compositions comprising an antibiotic agent other than penicillins, i.e., dactinomycin. The specification does not enable any person skilled in the art to which it pertains, with which it is most nearly connected, to use the invention commensurate in scope with these claims, see claim 23-24, lines 1-2, and page 21, lines 13-19 of the specification.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the Disclosure.

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See below:

1) Nature of the invention

The claim is drawn to compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics.

2) State of the prior art

The reference Christensen et al. US 3,943,153 does not indicate which compounds/compositions of instant compounds may be useful in the claimed invention. Christensen et al. '153 is pertaining to (-)(Cis-1,2-epoxy propyl) phosphonic acid amide.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claim is drawn to compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics, by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claim is drawn to compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics, there would be little predictability in the scope of claimed compositions.

5) Amount of direction and guidance provided by the inventor.

The claim is drawn to compositions of compounds of formula (II) further

comprising an antibiotic agent without limitation of named antibiotics, i.e., antibiotics other than penicillins, i.e., dactinomycin.

6) Existence of working examples.

The claim is drawn to compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics, the specification provides only limited examples of compositions.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous products in order to obtain "compositions of compounds of formula (II) further comprising an antibiotic agent without limitation of named antibiotics" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. incorporation of limitation of "an antibiotic agent" or "beta-lactam

antibiotic", i.e., penicillins, , would obviate the rejection, see claim 23-24, lines 1-2, and page 21, lines 13-19 of the specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 and 17 recites the limitation "X is a fused carbocyclic" in line 1. There is insufficient antecedent basis for this limitation in the claim. The limitation "X is a fused carbocyclic" is not found in the base claim 5 or 16. Correction is required, see page 14, lines 8-13, of the specification.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

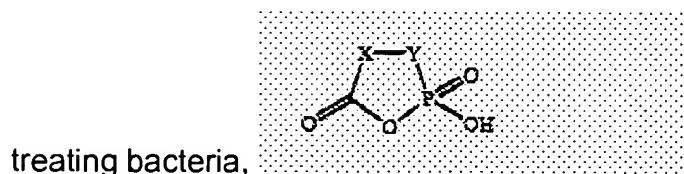
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 16-18 and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of Besterman et al. US 6,608,046. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compositions of compounds of formula (II) as agent treating bacteria. The instant compositions have been found on pages 4-20 of the specification.

Besterman et al. claim compositions of compounds of formula (II) as agents



The difference between instant claims and Besterman et al. '046 is that Besterman et al. silence the instant species of compounds of formula (II), i.e., instant claim 22.

One having ordinary skill in the art would find the claims 16-18 and 22-24 prima facie obvious because one would be motivated to employ the compounds of Besterman

et al. '046 to obtain instant claimed compositions, i.e., a composition comprising compounds of formula (II).

The motivation to make the claimed compositions derives from the expectation that the instant claimed compositions derived from known Besterman et al. compounds/compositions would possess similar activities (i.e., agents treating bacteria) to that which is claimed in the reference.

Objection

10. Claims 5-7, 16-18 and 22-24 are objected to as containing non-elected subject matter, i.e., fused heterocyclic, heteroaromatic ring, or heteroarylene, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the page 2 *supra*.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from


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the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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December 20, 2005